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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/655,073	09/04/2003	Ralf M. Luche	200125.418C1	5471

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SEED INTELLECTUAL PROPERTY LAW GROUP PLLC  
701 FIFTH AVE  
SUITE 6300  
SEATTLE, WA 98104-7092

EXAMINER

SAIDHA, TEKCHAND

ART UNIT PAPER NUMBER

1652

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/655,073	<b>Applicant(s)</b> LUCHE ET AL.	
	<b>Examiner</b> Tekchand Saidha	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1, 10 and 15-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1, 10 and 15-53 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***RESTRICTION***

1. Applicants' preliminary amendment filed 9.4.2003 is acknowledged. As per the amendment claims 2-9 & 11-14 have been canceled and new claims 50-53 have been added. Claims 1, 10, 15-53 are currently pending in this application.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 45-46 & 50-52 drawn to DSP-11 (Dual specificity phosphatase - SEQ ID NO : 2 and mutants), classified in class 435, subclass 194.
- II. Claim 53, drawn to a vector comprising a polynucleotide encoding DSP-11, classified in class 435, subclass 320.1.
- III. Claims 10 & 22-25, drawn to anti-sense strand (coding strand) and method of detecting DSP-11 polypeptide expression, classified in class 435, subclass 6.
- IV. Claims 15-21, drawn to antibody, composition and method of use, classified in class 424, subclass 130.1
- V. Claims 26-29, drawn to method of screening an agent that modulates (inhibits/activates) DSP-11 activity, classified in class 435, subclass 69.2.

Art Unit: 1652

- VI. Claims 30-32 & 42, drawn to method of screening an agent that modulates DSP-11 activity [different steps], classified in class 435, subclass 69.2.
- VII. Claims 33-41, drawn to a method of modulating a proliferative, differentiative and survival response of a cell, classified in class 435, subclass 376/377.
- VIII. Claims 43-44, drawn to a method of treatment of a patient afflicted with a disorder associated with DSP-11 activity, classified in class 424, subclass 94.5.
- IX. Claims 47-49, drawn to a method of screening a binding molecule of DSP-11, classified in class 435, subclass 21.

2. The inventions are distinct, each from the other because of the following reasons:

3. The vector comprising the nucleic acid of Group II and the DSP-11 of Group I are independent chemical entities and require different searches. They are chemically and biologically distinct molecules. Additionally, the DNA contained in the vector has other functions besides encoding the enzyme. Since the DSP-11 polypeptide and the DNA contained in the vector are biologically and chemically distinct, the manner of using the DNA contained in the vector may not necessarily involve the enzyme. At the minimum, the enzyme can be used to delineate molecular weight parameters in protein gel electrophoresis. The enzyme and DNA contained in the vector have fundamentally different

Art Unit: 1652

molecular structure, each with its own set of functionality. Enzyme, for example is biologically active, whereas DNA contained in the vector encoding the enzyme, is not. Inventions of Group I and III are distinct for the same reasons as Inventions of Groups I and II.

4. Inventions of Group I and IV are distinct because protein and antibody are chemically and biologically distinct molecules. Antibody and protein have fundamentally different molecular structure, each with its own set of functionality. Antibodies, for example, are formed in the B-cells and are useful for binding to particular residues. Proteins do not function to bind in the particular immunological way that antibodies do, and therefore have different specificities for different substrates, and do not purport to have the kinds of specific activity that antibodies have.

5. Inventions II and IV or III and IV are patentably distinct from each other. The nucleic acids, vectors, cells, and methods of Group I or the anti-sense strand or molecule of Group III and the antibodies and methods of Group IV do not require each other for their practice; have separate utilities, such as use of nucleic acids, vectors, cells, and methods to recombinantly produce protein versus use of the antibodies to detect proteins; are physically, chemically and biologically different from each other; and are subject to separate manufacture and sale from each other. These groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification.

Art Unit: 1652

6. Inventions I & V-IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. ' 806.05(h)). In the instant case the DSP-11, as claimed in Group I, can be used in a materially different process other than the methods in Group V-IX, such as in the preparation of antibodies. Similarly the polynucleotide of Group II can be used in a materially different process other than developing a method of detection or a method of identifying a compound, or treatment method, etc., of Groups V-IX.

7. The methods of Inventions V-IX are related in that each method requires the use of Invention I or II or III or IV. However, the steps and end points of the methods are wholly different and therefore Inventions V-IX are patentably distinct.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Art Unit: 1652

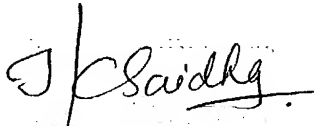
10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventor ship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventor ship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

10. 5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha whose telephone number is (571) 272 0940. The examiner can normally be reached on 8.30 am - 5.00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272 0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1652

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Tekchand Saidha  
Primary Examiner, Art Unit 1652  
Recombinant Enzymes, E03A61 Remsen Bld.  
400 Dulany Street, Alexandria, VA  
Telephone : (571) 272-0940

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